

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Prakash Subbiah on 9/16/09 and 9/30/09.

2. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 9/16/09 and 10/1/09, attorney requested an extension of time for one (1) MONTH(S) and authorized the Director to charge Deposit Account No. 50-3355 the required fee of \$65:00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the claims,

Cancel claims 1, 3 and 7-10.

In claim 4, line 10, after "skin of" substitute ---the--- for "a"

In claim 4, line 12, after "into" substitute ---the--- for "a"

In claim 6, line 1, after "polymer" substitute ---has--- for "comprises"

The listing of claims below will replace all previous versions:

Claims 1-3 (Canceled).

Claim 4. (Currently Amended) A method of producing an individual, surgically implantable implant which is surgically implanted underneath the skin of a patient for delivery of steady state concentrations of haloperidol to the patient for 5 months or more comprising: (a) dissolving between about 20% and 40% haloperidol and a biodegradable polymer consisting essentially of polylactide or lactide-co-glycolide copolymer in acetone; (b) solvent casting the haloperidol and biodegradable polymer solution to produce a completely dry haloperidol-polymer material; and (c) molding under compression the dry haloperidol-polymer material at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of [a] the patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more, and is removable following implantation into [a] the patient in the event the patient exhibits unwanted side effects following implantation.

Claim 5. (Canceled).

Claim 6. (Currently Amended) The method of claim 4 wherein the biodegradable polymer [comprises] has 50-100% polylactide and 0-50% polyglycolide.

Claims 7-10. (Canceled).

#### **Reasons for allowance**

3. The following is an examiner's statement of reasons for allowance: The primary reason for allowance of claims 4 and 6 is that the maximum theoretical loading capacity for haloperidol in PLG microspheres is around 10% in Cheng for an empirical haloperidol loading of 3.07 while between 20 and 40% haloperidol is loaded onto the PLG using acetone as solvent in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Examiner, Art Unit 1618